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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,112	07/27/2000	Se-Jin Lee	JHU1120-11	2658

7590 10/31/2008
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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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10/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/628,112	Applicant(s) LEE ET AL.	
	Examiner Marianne P. Allen	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,34,37,40 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44 and 45 is/are allowed.
- 6) ☒ Claim(s) 1,34,37,40,43,46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/15/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 7/24/08 have been fully considered but they are not persuasive.

Claims 1, 34, 37, 40, and 43-47 are pending and under consideration.

Double Patenting

The terminal disclaimer filed on 6/24/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 7,179,884 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 34, 37, 40, 43, 46, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al. (U.S. Patent No. 6,369,201 B1).

This rejection is maintained for reasons of record.

Particular embodiments embraced by claim 1 are substantially purified peptides consisting of about amino acids 1-20 of SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, or 16 (the promyostatin signal peptide domain). These concepts are not disclosed by parent application 09/124,180.

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Particular embodiments embraced by claims 34, 37, and 46 are substantially purified peptides consisting of amino acids 20-262 of SEQ ID NOS: 2, 8, 10, 12, 14, or 16 or consisting of about amino acids 20-263 of SEQ ID NOS: 4 or 6 (the promyostatin prodomain). These concepts are not disclosed by parent application 09/124,180.

Particular embodiments embraced by claims 40, 43, and 47 are substantially purified peptides consisting of about amino acids 268-375 of SEQ ID NOS: 4 or 6 or consisting of amino acids 267-374 of SEQ ID NOS: 2, 8, 10, 12, 14, or 16, (the promyostatin myostatin domain). These concepts are not disclosed by parent application 09/124,180.

The parent application does not disclose nor contemplate as the invention a peptide limited to the promyostatin signal peptide domain, promyostatin prodomain or promyostatin myostatin domain as set forth in the claims. The claims embrace these smaller domains and are not limited to the full length polypeptides.

As such, benefit to the filing date of parent application 09/124,180 is denied for claims 1, 34, 37, 40, 43, 46, and 47. The effective filing date for these claims is considered to be 27 July 2000.

Barker et al. is valid prior art against the instant claims as this application was filed on 18 February 1999.

Barker et al. discloses the full length sequences for human, murine, rat, chicken, baboon, bovine, porcine, ovine, turkey, and zebrafish promyostatin polypeptides. Barker's SEQ ID NOS: 29, 27, 28, and 30 corresponding directly to instant SEQ ID NOS: 4, 6, 2, and 10, respectively. Barker's SEQ ID NOS: 31-34 and 36 have a conservative substitution in a single position with

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respect to instant SEQ ID NOS: 12, 14, 16, 8, and 20, respectively. Barker's SEQ ID NO: 35 has two mismatches to instant SEQ ID NO: 18. Particular fragments of these polypeptides are also disclosed. See at least Figure 1A-1D and column 3, lines 25-45. Note that none of the mismatches occurs in the promyostatin myostatin domain and only one mismatch (for SEQ ID NO: 18) occurs in the promyostatin signal peptide domain. However, as the mismatch in SEQ ID NO: 18 is at amino acid three, this is considered to be within the claim limitation of "about 1-20."

This disclosure anticipates the instant claims as the claims all use "comprising" or open language and include the full length sequences as well as the fragments disclosed by Barker et al.

Applicant's arguments remain unpersuasive with respect to the priority date. Barker et al. (U.S. Patent No. 6,369,201) remains valid prior art and the 102(e) rejection is maintained. As set forth in the prior Office actions, the claims embrace substantially purified peptides limited to the promyostatin signal peptide domain alone, the promyostatin prodomain alone, the promyostatin myostatin domain alone. These concepts are not disclosed by parent application 09/124,180. Nothing applicant has pointed to shows contemplation of these smaller peptides as being part of the invention contemplated or disclosed in the parent application. Again for example, a discussion of where the signal peptide is found is not a disclosure that the signal peptide alone was of interest or part of the contemplated invention. The parent application does not contemplate polypeptides having only these smaller domains. The parent application contemplates the full length sequences.

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Applicant points to Example 2 of the parent application. A statement that cleavage at a particular site would result in a 109 amino acid fragment does not show contemplation of a substantially purified peptide as claimed. This example does not disclose actual cleavage and the examples are only with respect to mouse and human sequences. See also discussion with respect to Example 4, below.

Applicant points to Example 3 of the parent application. This example discloses cloning the murine and human GDF-8 sequences. Figures 2A-2B and 5A-5B box the processing sites. Discussion of proteolytic cleavage sites does not show contemplation of a substantially purified peptide as claimed. It does not disclose the presently claimed invention.

Applicant point to Example 4 of the parent application. This example discloses using amino acids 268-376 of human or mouse GDF-8 for production of antibodies. Note this example doesn't specify whether it was mouse or human, but preceding Example 3 indicates that these portions of the human and mouse sequence are identical. The claims are not limited to the human and mouse sequences and this example does not contemplate this or similar fragments from other species of GDF-8. Applicant is reminded that the claims "the peptide comprising a promyostatin myostatin domain corresponding to amino acid residues about 267 or 268 to 374 or 375 of a full length promyostatin polypeptide" (see claim 40) and "corresponding to amino acid residues about 267 to 374 of the promyostatin polypeptide" (see claim 43). See also claim 47 which recites amino acids 268-375 of SEQ ID NO: 4 (the murine sequence). Note that this example doesn't match the endpoints in these claims nor does it contemplate variable endpoints for each of the recited sequences.

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Applicant points to Example 5 of the parent application. This example discloses producing fusion proteins containing heterologous sequences using the murine GDF-8 sequence. It does not disclose the presently claimed invention.

The parent application does not disclose the presently claimed inventions. It does not disclose substantially purified peptides consisting of only the smaller polypeptides embraced by the claims for each of the species recited in the claims.

A fair reading of the parent application would not readily convey to one of ordinary skill in the art that what is presently claimed was the contemplated invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712.

The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa